Original Article

The Effectiveness of Cognitive-Behavioral Approach in Alleviation of Depression, Anxiety and Stress Risks in Diabetic People

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Abstract

Objective: Stress, anxiety, and depression affect the diabetic patient by causing symptomatic changes. Considering the destructive effects of psychological symptoms on the health status of diabetic people, our aim was to investigate the effectiveness of cognitive-behavioral therapy (CBT) in improving the psychological outcomes of diabetic patients.

Method: This trial is a quasi-experimental type that uses a pretest-posttest design with a control group. A total of 62 people were selected based on the inclusion criteria and randomly divided into two experimental and control groups. All subjects in the intervention group underwent CBT training twice a week for eight sessions, while those in the control group did not receive this intervention. Before and following the intervention, the depression, anxiety and stress scale (DASS-42) was utilized to evaluate the psychological symptoms of all participants. The data were analyzed through analysis of covariance (ANCOVA) and SPSS-23 software.

Results: There were no significant differences between the two groups in terms of age, gender, marital status, parenthood, and education level (P > 0.05, n = 30 in each group). Additionally, there was no significant difference between the mean DASS-42 scores before the intervention (P > 0.05). However, after the intervention, the experimental group exhibited reduced levels of depression, anxiety, and stress compared to the control group (P < 0.001). The values of Eta for depression, anxiety, and stress subscales were equal to 0.809, 0.669 and 0.776, respectively, which means that 80.9%, 66.9%, and 77.6% of the changes in these symptoms in the experimental group are related to the training received through the CBT approach.

Conclusion: It can be concluded that diabetic patients who suffer from psychological symptoms can benefit from the CBT approach to reduce their stress, anxiety, and depression levels.

Key words: *Anxiety; Cognitive Behavioral Therapy; Clinical Trial; Diabetes Mellitus; Depression*

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Diabetes is a prevalent chronic metabolic disorder worldwide. Its increasing prevalence is one of the main public health concerns in the 21st century (1). Based on the report of the World Health Organization (WHO), the prevalence of diabetes in Iran is more than 8% (2). While hereditary family history is a decisive factor in the onset of diabetes, its sudden onset is often associated with stress or depression, which disturbs the vital balance in susceptible individuals (3). Depressive symptoms have been shown to be related to various chronic medical diseases such as diabetes (4). The odds ratio of comorbid depression for diabetic people is twice that of the general population (5). In comparison to individuals with diabetes alone, patients with both diabetes and comorbid depression show greater functional disabilities, worse glycemic control, longer hospital stays, worse self-care ability, and an increased risk of mortality and morbidity (6-9). Therefore, the comorbidity of depression and diabetes has significant implications for patients' well-being, illness management, and clinical outcomes (10). Moreover, anxiety is observed in about 14% of diabetic patients (11).

As a chronic disease, diabetes requires patients to adapt to several routine activities such as engaging in physical activity, maintaining a healthy diet, adhering to medication, and being cautious about any complications. These conditions may result in diabetes-related distress, low self-esteem, loss of control, and anxiety and depressive traits in diabetic patients (12). All these symptoms indicate the need for changes that a diabetic patient must make to effectively manage the illness. Cognitive-behavioral therapy (CBT) is a well-known form of psychotherapy that has been demonstrated to have positive effects on a variety of psychological conditions in different populations (13, 14). This method provides an organized way for clinical psychologists to work with patients and empower them to better deal with their problems. For example, this therapeutic approach can be effective for those people who have problems such as inability to control anger and myopia, as well as in cases with physical problems such as fatigue and chronic pain (15). This approach incorporates a range of cognitive and behavioral techniques, such as problem-solving, stress management, cognitive restructuring, and relaxation. CBT is efficient in alleviating symptoms of anxiety and depression in people with physical illnesses (16). The application of CBT in the management of blood sugar control and associated mental consequences in diabetic patients have been reported with different outcomes (17-20). For example, Welschen *et al.* and Cummings *et al.* revealed that six sessions of CBT can improve depressive symptoms in patients with diabetes up to six months after the intervention (20, 21). However, Safren *et al.* reported no significant improvement in psychological symptoms of diabetic patients after 9-11 sessions of CBT (17). Recent systematic review and meta-analysis studies have shown that although CBT can affect the psychological symptoms of diabetic patients, the heterogeneity of the main findings and the existence of some contradictions among the results make it difficult to draw definitive conclusions in this area. These studies have concluded that more studies in this field are needed in different clinical and non-clinical populations and in various cultures to reach a definitive consensus (14, 19, 22). One of the limitations of previous studies has been the wide age range of participants, which could have influenced their findings. For this reason, in this study, we tried to address this issue by narrowing the age range of diabetic patients and including only middle-aged people.

Given the high prevalence of diabetes in Iran, it is essential to focus on prevention, recognition, and treatment of mental disorders such as anxiety, stress, and depression, as they have a crucial role in controlling diabetes. Depression, anxiety, and stress affect the diabetic patient by causing symptomatic changes such as excessive increase or decrease in blood sugar, fatigue, sweating, and headache (7, 11). Therefore, considering the destructive effects of psychological symptoms on the health status of diabetic patients and considering the aforementioned points, our aim was to explore the effectiveness of an eight-session CBT intervention on the psychological outcomes of diabetic individuals.

Materials and Methods

Participants
This study was based on a single-blind quasi-experimental approach utilizing a pretest-posttest design with a control group. The statistical population included all diabetic patients aged between 40-60 who were referred to the diabetes center of Najaf Abad in May 2021. The sample size was calculated to be 60 subjects considering 95% confidence interval, 0.35 effect size, and 0.05 margin of error. Therefore, 62 individuals with diabetes were chosen via a permutation block random sampling approach and then randomly assigned to either the experimental or control group (31 people in each group). The criteria for entering this research include having diabetes based on official diagnosis, having no other physical or mental illness (based on a psychiatrist's interview), having consent to participate in our research, being within the age range of 40 to 60 years, having at least enough literacy to understand and answer the questions. The criterion for excluding from the study was frequent absences from therapy sessions and simultaneous use of other psychotherapy approaches.

Study procedure
First of all, we described the research project and its purpose to all participants and obtained a signed consent form from them to participate in the trial. Then the subjects were divided into four blocks and randomly assigned to either the experimental or control group based on the random permutation block sampling approach. Before the intervention, the data collection process was performed by administering the Depression Anxiety and

Stress Scales (DASS-42 questionnaire) to both groups as a pretest. In the next step, the subjects of the experimental group participated in eight 90-minute sessions of the CBT intervention, which were held twice a week for four consecutive weeks. Meanwhile, the subjects in the control group received their standard treatment without the CBT intervention. After the end of the training course, the DASS-42 questionnaire was administered as a posttest to both the experimental and control group. To reduce potential bias in the results, the data of both groups were arranged as group 1 and group 2 and were provided to the statistical analyst of the project, who was blind to the nature of the groups.

Outcome measure

The DASS-42 questionnaire, which has 42 questions in a long form, was used to evaluate depression, stress, and anxiety in the patients. This questionnaire is based on a 4-point Likert scale that records data in four categories from "never" to "always" in three general dimensions of depression, stress, and anxiety (each dimension is measured by 14 questions). Lovibond and Lovibond in their research, which included 717 people, obtained similarity coefficient (Cronbach's alpha) of 81.91, 0.0 and 0.89 for three subscales of depression, anxiety and stress, respectively (23). In another study, Asghari Moghadam *et al.* proved the reliability of the Iranian version of this scale and reported that the retest coefficients in a three-week interval for three subscales were 0.84, 0.89 and 0.90, respectively (24).

CBT intervention

In general, CBT allows people to understand their thoughts and feelings and practice new coping strategies to prevent serious psychological conditions. This approach typically requires at least four weeks of training. The CBT sessions in this research were held in a group format by an experienced clinical psychologist who specializes in the diagnosis of psychiatric illnesses and their treatment. The content of this CBT package has been validated by previous studies. The CBT training was carried out on the experimental group in eight 90-minute sessions on a weekly basis. Table 1 represents a summary of the content of these sessions.

Table 1. Summary of Cognitive-Behavioral Therapy Sessions to Reduce Anxiety and Depression in Diabetic People

Sessions	The topic of every session
1	General program information- confidentiality- purpose and introduction of CBT approach- stress management techniques - relaxation training
2	The effect of thoughts on mood- positive thoughts- physical effects of stress- introducing muscle relaxation for 16 muscle groups- instructions for muscle relaxation
3	Effective factors on the increment of thoughts that improve mood- reducing thoughts that cause unpleasant feelings- awareness about automatic thoughts- practicing to raise awareness regarding the physical signs of stress- practicing mental reviewing- physical exercises- visualization exercises (thoughts, emotions and bodily sensations)
4	Negative thoughts and cognitive distortions (all-or-nothing thinking)-extreme generalization- mental filter-ignoring positive things- quick conclusions- mind reading- prediction error (magnification or minimization)- emotional reasoning- labeling - personalization
5	Characteristics of automatic negative thoughts- main aspects of negative thoughts- methods of recognizing negative thoughts- recognition of unpleasant emotions
6	The difference between reasonable and irrational self-talk- practicing to identify logical and irrational self-talk- steps to replace logical thoughts- creating logical answers - creating enjoyable activities
7	Overcoming negative thoughts using the ABCD method- the importance of social support- social support network- various types of short-term, midterm-term, and long-term goals
8	Conclusion- practicing the skills learnt in the previous sessions and the need to apply the skills when dealing with stressful situations and depression to reduce symptoms.

Statistical analysis

Mean, frequency, frequency percentage and standard deviation were used for descriptive statistics. In addition, tests of normality (Shapiro–Wilk test) and homogeneity of variances were applied as a prerequisite for covariance analysis for inferential analysis. Changes in outcome measures following the treatment sessions were compared between the two groups through ANCOVA (with adjustment for baseline variables). SPSS 23 software was used for statistical analysis and the significance level was set at 0.05.

Ethical considerations

This research was confirmed by the Ethical Committee of University of Isfahan (IR.UI.REC.1401.089), and registered in the Iranian registry of clinical trials (IRCT20180607039997N1). All subjects were informed about the objectives of the research and signed an informed consent form.

Results

A total of 87 patients were screened, of whom 62 were included in our study. However, one subject from each group did not complete the post-intervention assessment and were subsequently excluded from the final analysis (Figure 1). The average age of the participants was 48.54 ± 6.12 years (the age range of 40-60 years). About 23% of the participants were male and 77% were female. Independent t-test and chi-square were utilized to compare the sociodemographic variables of both the control and experimental group. As summarized in Table 2, there were no significant differences between the two groups in terms of age, gender, marital status, parenthood, and education level ($P > 0.05$).

All subjects completed the DASS-42 questionnaire both in the pretest and posttest with no data leakage. The mean scores of DASS-42 subscales are summarized in Table 3 for the two groups and compared at each assessment time. As shown, there was no significant difference between the mean DASS-42 scores before the intervention ($P > 0.05$). However, after the intervention, significant differences

were observed in the mean DASS-42 scores between the groups ($P < 0.001$). In fact, after eight sessions of CBT, the experimental group exhibited reduced levels of depression, anxiety, and stress compared to the control group.

The ANCOVA revealed that there were significant differences between the experimental and control group in terms of depression, anxiety and stress symptoms ($P = 0.001$). It should be noted that the Shapiro-Wilk test indicated that the data followed a normal distribution ($P > 0.05$). The results of the ANCOVA analysis are depicted in Table 4. As shown, our CBT intervention reduced depression, anxiety, and stress levels in the experimental group. The values of Eta for depression, anxiety, and stress subscales were equal to 0.809, 0.669, and 0.776, respectively. This suggests that 80.9%, 66.9%, and 77.6% of the changes in these symptoms in the experimental group are attributed to the training received through the CBT approach. The statistical power for depression, anxiety, and stress subscales were equal to 1, revealing that no error occurred and the sample size was enough for this research.
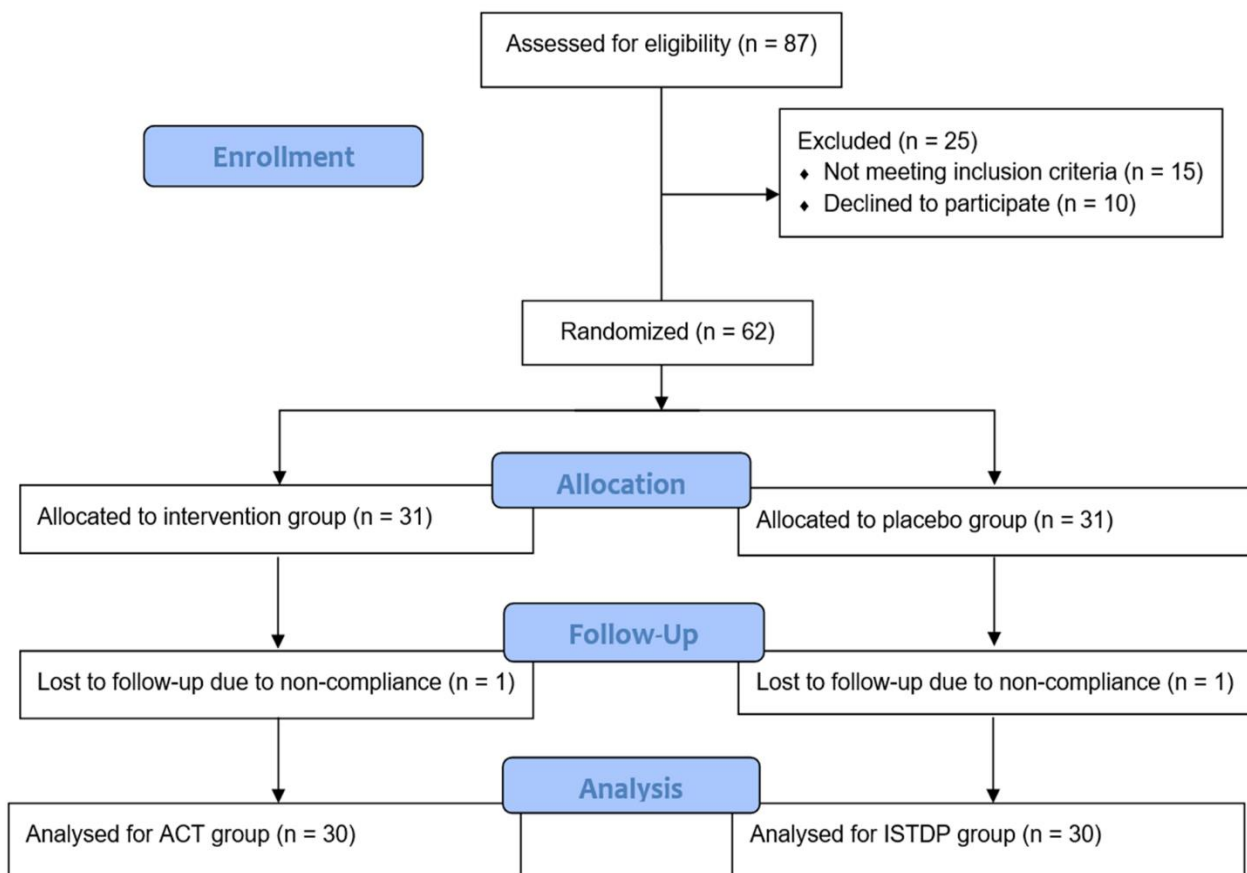

Figure 1. Consort Flow Diagram of Different Steps Involved in the Randomized Controlled Trial to Investigate the Effect of Cognitive-Behavioral Therapy on Psychological Symptoms in Diabetic Patients

Table 2. Sociodemographic Information of the Patients with Diabetes in each Experimental and Control Group

Sociodemographic Variables	Experimental Group n (%)	Control Group n (%)	P-value
Gender			
Male	6 (20.0%)	8 (26.7%)	0.54
Female	24 (80.0%)	22 (73.3%)	
Age (Mean ± SD)	49.41 ± 6.71	47.84 ± 7.10	0.38
Marital status			
Single	9 (30.0%)	7 (23.3%)	0.56
Married	21 (70.0%)	23 (76.7%)	
Being a parent			
Yes	18 (60.0%)	17 (56.6%)	0.79
No	12 (40.0%)	13 (43.4%)	
Education			
Diploma	10 (33.3%)	10 (33.3%)	
Associate degree	4 (13.3%)	6 (20%)	0.50
Bachelor	16 (53.4%)	14 (46.7%)	

Table 3. Comparison of Mean (Standard Deviation) Scores of the Depression, Anxiety, and Stress Scales (DASS-42) between Experimental and Control Group before and after Treatment

Outcome measures	Assessment time	Experimental group (n = 30)	Control group (n = 30)	P-value (t-statistic)
Depression	Pre (m ± SD)	36.73 ± 4.54	37.53 ± 2.69	0.91 (0.10)
	Post (m ± SD)	22.86 ± 4.32	37.60 ± 2.86	< 0.001 (15.58)
Anxiety	Pre (m ± SD)	29.93 ± 3.53	29.40 ± 3.22	0.54 (0.60)
	Post (m ± SD)	20.60 ± 3.45	29.73 ± 2.89	< 0.001 (11.11)
Stress	Pre (m ± SD)	37.60 ± 3.62	37.40 ± 2.74	0.81 (0.24)
	Post (m ± SD)	22.80 ± 2.93	37.40 ± 2.66	< 0.001 (20.21)

Table 4. Results of Analysis of Covariance (ANCOVA) on Mean Scores of Depression, Anxiety and Stress in Post-Test

Outcome measures	Source	Total sum of squares	Degrees of freedom	Mean square	F-value	P-value	Eta effect size	Statistical power
Depression	Pre-exam	3.632	1	3.632	0.261	0.614	0.010	0.051
	Group	1591.478	1	1591.478	114.372	0.001	0.809	1.000
	Error	371.415	57	13.915				
	Total	29429	60					
Anxiety	Pre-exam	3.779	1	3.779	0.342	0.564	0.013	0.087
	Group	558.266	1	558.266	50.454	0.001	0.669	1.000
	Error	276.619	57	11.065				
	Total	19911	60					
Stress	Pre-exam	15.754	1	15.754	0.935	0.343	0.036	0.153
	Group	1455.218	1	1455.218	86.381	0.001	0.776	1.000
	Error	421.160	57	16.846				
	Total	29219	60					

Discussion

This trial was performed with the aim of determining the impact of CBT on reducing the symptoms of stress, anxiety, and depression in middle-aged diabetic patients. Our trial revealed that the psychological symptoms of stress, anxiety, and depression were considerably reduced following eight sessions of CBT over a period of one month. The findings of this research are in line with the findings of previous trials (25-30). The positive influence of CBT in alleviating depression is consistent with findings reported for the efficacy of CBT in improving depressive symptoms in people with various illnesses such as stroke, chronic pain, post-traumatic stress disorder, and social phobia (31, 32). In explaining the reduction of depressive symptoms as a result of CBT training, it can be pointed out that this approach is associated with depression treatment by improving dysfunctional cognition. Indeed, depressive mood is associated with uncontrolled negative beliefs and thoughts as well as dysfunctional behaviors (33). CBT models can be useful in modifying health-related beliefs and behaviors in diabetic patients (22). Therefore, the alleviation of depressive symptoms may be related to cognitive reconstruction in the patients. With the help of CBT training, many cognitive distortions such as catastrophizing and negative prophecies can be modified (34). However, previous studies have shown that a long training course (at least six weeks) is required to achieve such a cognitive reconstruction (14, 35). In contrast, our trial showed that eight sessions of CBT in a four-week training course can be effective in achieving a positive treatment goal. Furthermore, some previous trials have attempted to focus on a diabetes-specific manualized CBT course to achieve better clinical outcomes (36-38). However, as confirmed in our research, a recent meta-analysis study found that traditional CBT with its general structures can be more effective in improving depressive symptoms in diabetic patients compared to customized CBT courses (14).

Unlike depression symptoms, which have been the focus of many studies, very few studies have targeted anxiety and stress symptoms in diabetic patients. However, it has been shown that anxiety and stress are prevalent in patients with diabetes, which negatively impact the management of diabetes (39, 40). Consistent with our findings, Chapman *et al.* suggested in their systematic review that CBT-based treatments can be efficacious in alleviating anxiety in diabetic patients (34). However, Yang *et al.* reported in their meta-analysis that CBT did not have a considerable effect on anxiety and stress symptoms in diabetic patients. They attributed this finding to the paucity of original articles targeting stress and anxiety symptoms and suggested that future CBT studies focus on these symptoms in diabetic patients (14). Therefore, in this trial, in addition to depression symptoms, we also targeted anxiety and stress and found positive effects of CBT on these psychological symptoms. This result was expected, given that CBT has been demonstrated to be effective in managing anxiety and is also superior to psychopharmacology for anxiety disorders (32). Using cognitive methods, such as practicing identifying negative thoughts, knowing the difference between rational and irrational self-talk, and steps to replace negative thoughts, as well as recognizing appropriate ways to deal with different situations, are among the options that justify the reduction of these psychological symptoms in the experimental group.

Limitation

The most important limitation of this study was the lack of follow-up evaluations due to the COVID-19 pandemic and the unwillingness of most of the participants for follow-up evaluations. Consequently, it was not possible to follow up the mental health status of the patients over a specific period of time. Therefore, it is suggested that in upcoming studies, follow-up assessments along with CBT reminder sessions should be included over longer periods of time. Furthermore, examining a small sample size in a single center is another limitation of this study. Thus, implementing a comprehensive program to explore the effectiveness of CBT in larger populations of diabetic patients in a multicenter design can help us reach more definitive findings. Finally, the lack of physiological evaluations of the patients is another limitation of this research, which was due to budget limitations.

Conclusion

It seems that training the CBT approach through relaxation, cognitive methods of replacing negative thoughts, and learning the necessary skills to shift focus from negative thoughts can be effective in improving the mental health of diabetic patients. Indeed, it can be concluded that regular CBT sessions can improve the lifestyle of diabetic patients and decrease psychological symptoms such as stress, anxiety, and depression as well as behavioral problems in these patients. Considering the high prevalence of diabetes and its high burden and treatment costs, CBT treatment is recommended as an effective part of medical care for accelerating the recovery process of patients.

Acknowledgment

Conflict of Interest

None.

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